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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,941	07/25/2003	Pamela T. Manning	01073/1 US	3233

7590 08/01/2005

Pharmacia Corporation
Corporate Patent Department
P.O. Box 1027
Chesterfield, MO 63006

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,941	MANNING ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Reply filed May 26, 2005 is acknowledged. Claims 1-43 remain under consideration.

In the last Office Action claims 1-43 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91-108 of U.S. Patent No. 6,586,474. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed compounds are encompassed in the patent for use in the treatment of inflammation-related disorders. Inflammatory bowel disease, ulcerative colitis, gastritis and ileitis, *inter alia*, are inflammation-related disorders.

Applicants choose to hold this rejection in abeyance. The rejection of record under the judicially created doctrine of obviousness-type double patenting is maintained.

Claims 1-43 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention in the last Office Action. The claims are directed to the treatment of any condition or disease of the gastrointestinal tract involving an overproduction of nitric oxide by inducible nitric oxide synthase (iNOS). The specification provides support for the administration of various nitric oxide synthase inhibitors that decrease the rise in plasma nitrite/nitrate levels, an indicator of the production of nitric oxide induced by endotoxin in Table I. Table II demonstrates an ability of various compounds to inhibit inducible nitric oxide synthase activity *in vivo*. It

was asserted the instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation.

Applicants argue methods of assaying efficacy of iNOS inhibitors in gastric epithelial cells are recited and pharmaceutical compositions are described.

Applicants' arguments are not persuasive and the rejection of record under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record. Methods of assaying efficacy of iNOS inhibitors in gastric epithelial cells and pharmaceutical compositions do not provide support for the methods as claimed. The claimed invention relates to treatment of any condition or disease of the gastrointestinal tract involving an overproduction of nitric oxide by inducible nitric oxide synthase. Claim 1 additionally is drawn to the prevention of any condition or disease of the gastrointestinal tract involving an overproduction of nitric oxide by inducible nitric oxide synthase. The unpredictability observed with single agent therapy is compounded when a combination of agents is employed, as required by claims 14-43. The broad recitation "treating a condition or disease of the gastrointestinal tract involving an overproduction of nitric oxide by inducible nitric oxide synthase" is inclusive of many conditions that presently have no established successful therapies.

The disclosure is objected to for the following informalities: In claims 1 and 22 the designations "2HCl" and "2TFA" are dangling. A point of attachment should be shown.

The description of compounds of instant Formula II in claims 1 and 22 provides no probative value in view of the seven species shown at the end of the claims.

Appropriate correction is required.

One skilled in the art would know the definition of the term "prodrug" on page 38 of the specification. However, those "more preferred prodrugs" contemplated by Applicants are not.

It is noted the term "prevention" is deleted in claim 22. The term remains, however, in claim one.

Clarification is required.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

July 28, 2005